Bundesverband E-Commerce und
Versandhandel Deutschland e.V.
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Bundesverband E-Commerce und Versandhandel Deutschland e.V. bevh

Stakeholder Contribution

TRIS Notification 2026/0378/DE

Law on Data and Digital Innovation in Healthcare

Request for a Detailed Opinion under Article 6(2) of Directive (EU) 2015/1535

Notification number 2026/0378/DE

Notified draft dated 9 July 2026

Notification received 13 July 2026

Current standstill period ends 14 October 2026

Date of contribution 18 September 2026

Submitted by **Bundesverband E-Commerce und Versandhandel Deutschland e.V.**

The German **E-Commerce and Distance Selling Trade Association (bevh)** represents the interests of the online and mail-order retail sector in Germany, encompassing companies of all sizes and every conceivable form of retail (online, multichannel, catalog, TV shopping, platform retailers, and platform operators). bevh's members account for more than 90% of the industry's total revenue. In addition, more than 130 service providers from the e-commerce sector are affiliated with the association.

Executive Summary

The Bundesverband E-Commerce und Versandhandel Deutschland e.V. (bevh) invites the European Commission and the Member States to issue a detailed opinion under Article 6(2) of Directive (EU) 2015/1535 concerning notification 2026/0378/DE. The notified draft pursues legitimate objectives in public health, patient safety, security and interoperability. In particular, sections 363e, 370c and 374a, reinforced by the cumulative operation of sections 73(9a), 73(9b), 345a and 360c, may create obstacles within the meaning of Article 6(2) to the cross-border provision of digital services and to the supply and use of connected health products in the German statutory insurance market. Throughout this contribution, SGB V-E refers to the Fifth Book of the German Social Code as it would be amended by the notified draft. [1]

These obstacles do not depend on an express ban. Access to important parts of the German statutory healthcare market would depend on German-only digital gateways, approvals, confirmations and technical rules. The notified text often leaves the substantive criteria and procedures to bodies that also operate or govern competing public infrastructure. Providers established in another Member State may therefore have to redesign services or products for Germany, undergo additional national review and accept uncertain market-entry timing even where they already meet equivalent requirements elsewhere in the Union.

- **Prior agreement for KIM specialist procedures.** Section 363e SGB V-E requires agreement with gematik before a specialist procedure using the secure KIM email service may be made available. The scope is broad and the draft provides no binding decision period, exhaustive criteria, deemed approval or independent review.
- **Digital access architecture privileging public systems.** Sections 345a and 360c SGB V-E privilege systems operated by the National Association of Statutory Health Insurance Physicians. Together with the approval, confirmation and proof procedures for private systems under sections 73(9a), 73(9b) and 370c, this design risks crowding private providers out of a substantial and progressively expanding part of the digital patient journey. The procedures also lack complete statutory criteria and an equivalence route.
- **National conformity layer for connected products.** Section 374a SGB V-E combines mandatory interfaces, a gematik confirmation, BfArM registration, sickness-fund audit rules and a fee for connected aids and implants supplied through the German statutory insurance system.
- **EUDI Wallet timetable.** Section 291(8) SGB V-E sets 1 December 2028 for use as insurance proof and no later than 1 December 2030 for authentication. Where Article 5f of Regulation (EU) No 910/2014 as amended applies earlier, the directly applicable Union timetable must prevail.
- **Downstream technical rules.** Several decisive requirements will be set later by agreements, guidelines and procedures. Where those instruments prescribe compulsory technical specifications or rules for information society services, they should be notified under Article 5(1) of Directive (EU) 2015/1535 before adoption.

bevh does not submit that every national requirement in digital healthcare is incompatible with Union law. Germany may protect public health and organise its healthcare system. The concern is that, for the specific controls identified below, the notified draft and its explanatory memorandum do not demonstrate why the selected mechanism is necessary, why less restrictive safeguards would not

suffice, or how equivalent services and evidence from other Member States will be recognised. The amendments requested below would preserve the stated health and security objectives while reducing fragmentation of the internal market.

Summary of the provisions and requested safeguards

Provisions	Internal market concern	Requested safeguard
Sections 73(9a) and (9b), 345a, 360c and 370c	A publicly controlled default gateway bundles central patient-facing functions and is combined with national approval and confirmation procedures for private referral, appointment and booking systems. This risks de facto displacement from a substantial and expanding part of the digital patient journey.	Open interfaces, equal visibility, a voluntary right to connect, freedom to operate independent pathways, objective criteria, fixed deadlines, recognition of equivalent evidence and independent review.
Section 363e	Prior agreement by gematik is required before a KIM specialist procedure may be made available, while scope, criteria and timing remain open.	Use notification as the default or narrowly define any approval with published criteria, a decision deadline, reasoned decisions and review.
Section 374a	Connected aids and implants face German interface, confirmation, registration, audit and fee requirements as conditions for supply at the expense of statutory health insurance.	Avoid a second product approval and recognise EU standards, certificates and equivalent test results with proportionate transition rules.
Section 291 paragraph 8	EUDI Wallet use as insurance proof begins in 2028 and authentication may be deferred until 2030, which may extend beyond the directly applicable Union timetable where Article 5f applies.	Align the national timetable with Article 5f eIDAS and prohibit additional national identity barriers.

Purpose and Scope

This contribution examines the draft dated 9 July 2026 that Germany notified under number 2026/0378/DE. It focuses on provisions that regulate digital services or impose technical and conformity requirements on products. It does not address the policy merits of the German statutory health insurance system as such.

The analysis of sections 345a and 370c is confined to their cumulative and sector-specific effects on the sectors represented by bevh. The contribution's additional focus is on sections 73(9a), 73(9b), 291(8), 363e and 374a and on downstream technical rules.

Several elements of the draft support open digital markets. Section 370c expressly refers to open and standardised interfaces and non-discriminatory access. The July draft also gives health information technology and medical technology associations a consultative role in the agreement under section 360b. Section 339(1b) can facilitate remote pharmacy access by allowing prescription access data to demonstrate the temporal connection with treatment; the resulting access is limited to medication-plan data and prescription and dispensing data under section 341(2), point 1(b) and point 11. These elements should be retained and made operational through enforceable access and equivalence safeguards.

This contribution therefore concerns only sections 73(9a), 73(9b), 291(8), 345a, 360c, 363e, 370c and 374a SGB V-E, together with the later instruments required to implement them. The provisions appear at Article 1 points 6, 20, 57, 77, 83, 87 and 90 of the notified draft. The fee for the confirmation under section 374a appears in Article 14.

Union Law Framework

TRIS Review

Directive (EU) 2015/1535 covers technical specifications, other requirements affecting the marketing or use of products and rules specifically aimed at information society services. It also covers relevant administrative provisions and certain de facto technical regulations. Article 5(1) requires notification while substantial amendments remain possible and requires renewed notification where later changes significantly alter scope, add requirements or make them more restrictive. Under Article 6(2), the Commission or another Member State may deliver a detailed opinion where a draft technical regulation may create obstacles to the free movement of goods or, in the case of a draft rule on services, to the free movement of services or the freedom of establishment of service operators within the internal market. [2]

The German draft delegates material conditions to later agreements, guidelines, confirmation procedures and technical specifications. The Commission should therefore assess both whether the notified statutory provisions are sufficiently complete for an effective review and whether the downstream instruments must themselves be notified before they become binding. This is particularly important where compliance determines whether a system may be used by statutory healthcare providers or whether a connected product may be supplied through the statutory insurance system.

Free Movement and Digital Services

Articles 34, 49 and 56 TFEU protect the free movement of goods, freedom of establishment and freedom to provide services. Public health may justify restrictions under Article 36 TFEU and Member States retain responsibility for organising health services under Article 168(7) TFEU. Those powers must still be exercised consistently with Union law. Measures must be non-discriminatory, suitable and necessary, and their benefits must not be achievable through less restrictive means. [3]

For information society services, Article 4 of Directive 2000/31/EC prohibits prior authorisation or an equivalent requirement that is specifically and exclusively targeted at such services. Article 3 also limits restrictions on cross-border information society services, subject to defined public-interest safeguards and procedures. Digital appointment platforms, software services, remote pharmacy interfaces and telemedicine platforms can fall within this framework even where the underlying healthcare profession is separately regulated. [4]

Directive 2011/24/EU confirms that, for telemedicine, healthcare is provided in the Member State where the healthcare provider is established. National reimbursement and professional rules may apply within their lawful scope, but technical access design should not create an additional and unjustified disadvantage for a provider established elsewhere in the Union. [5]

Union Sector Rules

The draft also operates in fields covered by directly applicable or harmonised Union rules. Article 5f of Regulation (EU) No 910/2014 as amended establishes cross-border acceptance of European Digital Identity Wallets by public sector bodies and, in defined circumstances, private relying parties in sectors including health. Regulation (EU) 2017/745 protects the placing on the market and putting into service of compliant medical devices while preserving national competence over the organisation, delivery and financing of health services, including reimbursement. Regulation (EU) 2023/2854 establishes data-access duties for connected products, while Regulation (EU) 2025/327 develops a Union framework for interoperable electronic health data. National rules may address remaining sector-specific needs, but they should use Union standards and evidence wherever possible and avoid duplicative national conformity layers. [6] [7] [8] [9]

Digital Access and National Approval Procedures

Public Digital Gateways

Section 345a requires statutory health insurers, no later than 1 February 2028, to offer an ePA function for digital access to care. Appointment booking within that function must use the electronic system operated by the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung or KBV) under section 370a. The function must also provide access to the nationwide standardised initial assessment used by the appointment service centres. Section 360c further requires the KBV, from 1 January 2031, to provide a nationwide uniform digital needs-assessment system through those centres and through the ePA access function. These provisions appear at pages 43 to 46 and 60 to 63 of the notified draft.

The explanatory memorandum describes the gateway as complementary to established access routes and states that use of the ePA is not a prerequisite. The operative text does not formally prohibit a private platform from operating. It nevertheless bundles appointment booking, initial assessment, access to electronic referrals, telemedicine-related functions, consent-based communication through the secure instant-messaging service and personalisation of the initial assessment and needs-based appointment offers within the ePA interface, while key functions are routed through KBV-operated systems. In combination with sections 360c and 370c, this design risks crowding private providers out of a substantial and progressively expanding part of the digital patient journey.

The concern is therefore not an existing formal exclusion but a foreseeable risk of de facto displacement. A statutorily mandated default gateway, privileged access to the ePA user interface, integrated data flows and the absence of a statutory route to equal integration could materially reduce the contestable market and the visibility of competing services, particularly in a market shaped by network effects.

Established providers of digital appointment-booking and care-navigation services operate across borders within the Union. A provider established in another Member State may nevertheless need to integrate into a Germany-specific distribution channel to reach German insured persons and participating doctors. The statutory gateway provisions do not specify open application programming interfaces, equal presentation of equivalent services, neutral selection criteria or a voluntary right to connect.

Interoperability, security, quality, patient protection and data-protection objectives can be secured through objective and proportionate requirements applied to functionally comparable public and private services. Those objectives do not, without further justification, require exclusive routing through a publicly operated system. Germany could retain a public default service while giving qualified private services an enforceable option, but not an obligation, to connect on equal technical and visibility terms. Providers must remain free to operate independent booking and care pathways, and choosing not to integrate into a KBV-operated system must not lead to regulatory or practical disadvantages.

Approval of Referral and Appointment Systems

Section 73(9a) provides that, from 1 September 2029, contracted doctors may use only electronic referral programs approved by the KBV. Section 73(9b) provides that, from 1 January 2028, they may use only information technology systems for reporting appointments that have successfully completed a KBV confirmation procedure for the section 370a(5) interface and have been approved by the KBV. The KBV determines the form, content and quality requirements of the confirmation procedure in consultation with the relevant federal health-IT industry associations and the Federal Commissioner for Data Protection and Freedom of Information, and publishes a list of approved systems. The criteria for approving electronic referral programs under section 73(9a) are to be agreed in the federal framework contracts under section 82(1). These rules appear at page 14 of the notified draft.

These are market-access conditions for software and digital services. The statute itself does not set out a complete set of objective approval criteria, a maximum decision period, deemed approval, an obligation to give reasons, recognition of equivalent evidence from another Member State or a dedicated independent review mechanism. Consultation with industry and publication of an approved

list improve transparency but do not replace these safeguards. An open-ended national approval process is liable to delay entry, increase localisation costs and deter smaller cross-border suppliers.

Germany should define the essential criteria in the statute, require proportionate and technology-neutral evidence, set binding decision periods and provide rapid independent review. Equivalent security, interoperability and quality evidence produced under recognised Union or Member State schemes should be accepted unless the authority identifies a specific and reasoned deficiency relevant to the German system.

Rules for Private Booking Platforms

Section 370c requires the National Associations of Statutory Health Insurance Physicians and Dentists and the National Association of Statutory Health Insurance Funds to agree technical and procedural requirements for booking platforms used by contracted doctors and dentists. The agreement must cover accessibility, data protection, information security, open and standardised interfaces, non-discriminatory access, neutral allocation, advertising restrictions and a procedure by which platform operators prove compliance to the KBV. This provision appears at pages 70 and 71 of the notified draft.

The explanatory memorandum states that the agreement is to apply without distinction to booking platforms offered by the Associations of Statutory Health Insurance Physicians for freely bookable appointments outside separately regulated referral cases. The statutory design nevertheless creates an institutional asymmetry. The KBV operates the public appointment system under section 370a, will operate the public needs-assessment system under section 360c, participates in writing the rules for booking platforms and receives operators' proof of compliance. The separately regulated public system under section 370a is not expressly subjected to the same compliance assessment or to independent supervision of competitive neutrality.

Where a digital appointment-booking platform constitutes an information society service and is established in another Member State, Article 3(2) of Directive 2000/31/EC limits Germany's ability to impose additional requirements within the coordinated field. In Google Ireland and Others (C-376/22), the Court held that the derogation in Article 3(4) does not permit general and abstract measures applying indiscriminately to a category of information society services; the Court subsequently applied that approach in Airbnb Ireland and Amazon Services Europe (Joined Cases C-662/22 and C-667/22). The Commission should therefore request that Germany delimit the mandate in section 370c directly in the statute so that it cannot be used to impose general and abstract additional requirements within the coordinated field on providers established in other Member States. [4]

The final law should separate operational and conformity-assessment functions or place compliance decisions under a neutral body. To the extent that Germany may lawfully apply them, the substantive requirements intended to protect neutral patient choice, and the relevant compliance assessment, should apply equally to functionally comparable public and private services. The agreement should contain an equivalence route, binding timelines, reasoned decisions and an effective appeal. Affected platform providers and their representative associations, including those representing providers established in other Member States, should be consulted before the agreement is concluded. Because the future agreement will determine the technical conditions under which an online platform may serve

the German market, it should be notified under Directive (EU) 2015/1535 before it is adopted if it constitutes a rule on services or another technical regulation.

Prior Agreement for KIM Specialist Procedures

Section 363e is one of the most direct internal market concerns in the July draft. It provides that an organisation may use a standardised specialist procedure (Fachverfahren) within the secure KIM email service only in agreement with gematik. The agreement should be established no later than three months before the procedure is published or made available to a user group. The provision applies in particular to procedures established by law and to procedures expected to reach 10,000 messages per day or one terabyte per day with regular use. Because the text says in particular, those thresholds are not exhaustive. Gematik may also require information beyond the items listed in the statute. The provision appears at pages 68 and 69 of the notified draft.

Compared with the earlier May draft, the notified version changes an advance notification into a requirement for prior agreement. To the extent that section 363e applies to an undertaking offering an information society service, it may amount to prior authorisation or an equivalent requirement within Article 4 of Directive 2000/31/EC. In any event, it is a restriction capable of affecting services under Article 56 TFEU and a rule on services within Directive (EU) 2015/1535.

The draft does not state the grounds on which gematik may withhold agreement. It sets no binding period within which gematik must decide after receiving a complete file, no deemed agreement if the period expires, no express duty to issue a reasoned decision, no dedicated independent review mechanism and no recognition of equivalent security or capacity evidence. A supplier from another Member State therefore cannot determine in advance whether or when it may launch a KIM-based procedure in Germany. The uncertainty is itself capable of discouraging market entry.

The explanatory memorandum identifies capacity planning, operational continuity and performance as the objectives. Those objectives are legitimate, but the memorandum does not explain why they require prior agreement rather than advance notification backed by proportionate, risk-based intervention powers. Germany should retain advance notification as the default, publish objective technical and capacity requirements, and permit gematik to impose a temporary and reasoned restriction where a documented risk cannot be managed otherwise. If prior agreement is retained, the law should make the volume thresholds exhaustive, exempt pilots and low-volume procedures, define all decision criteria, impose a short decision period with deemed agreement, require written reasons and provide independent review. The procedure must be available electronically and on equal terms to providers established in any Member State.

Connected Aids and Implants

Section 374a applies from 1 January 2028 to aids and implants supplied at the expense of statutory health insurance where the product transmits patient data over public networks to the manufacturer or an affiliated undertaking. The product must allow its data to be transferred without charge, in suitable interoperable formats, to a digital health application listed under section 139e SGB V. Manufacturers must provide and open interfaces, provide technical support, report the interface to a BfArM register

and submit a gematik confirmation. The Competence Centre for Interoperability in Healthcare will set the technical and operational specifications under section 374a(4). Gematik will define the confirmation procedure and test criteria under section 374a(5). The National Association of Statutory Health Insurance Funds will issue a guideline governing the sickness funds' compliance checks under section 374a(6). Article 14 sets a fee of EUR 1,800 to EUR 2,200 for the confirmation. The relevant provisions appear at pages 72 to 74 and 116 of the notified draft.

These obligations prescribe product functionality, interface design, testing and conformity evidence and are liable to constitute technical specifications or other requirements under Directive (EU) 2015/1535 and to create obstacles to the intra-Union supply of covered products. They therefore meet the threshold for examination under Article 6(2). A manufacturer established in another Member State may have to modify a product or its backend specifically for the German reimbursement market, submit to an additional national confirmation and maintain a German registration. Importers, distributors and online sellers are affected downstream because products that do not meet these requirements will in practice face restrictions on supply at the expense of statutory health insurance. Section 374a(3) permits continued supply of non-compliant products only where this is medically necessary or required to ensure regular supply; sickness funds verify implementation under section 374a(6).

The objective of patient-controlled and interoperable data access is legitimate and consistent with the direction of the Data Act and the European Health Data Space. The draft should nevertheless avoid a Germany-specific interface or a second product approval. Article 1(15) of Regulation (EU) 2017/745 preserves national law concerning the organisation, delivery and financing of health services and medical care, including reimbursement. At the same time, Article 24 prevents Member States from refusing, prohibiting or restricting the making available or putting into service of devices that comply with the Regulation. The German process should therefore remain confined to the additional reimbursement-related interface obligation and must not reopen compliance with harmonised product-safety or market-access requirements. For all covered products, the German procedure should accept harmonised standards, common Union specifications, certificates and equivalent test results where they demonstrate the same requirement.

The final law should clarify that the confirmation concerns only the additional data-interface obligation and is not a general market or product-safety authorisation. Technical specifications should be platform-neutral and reusable across the Union. Germany should provide adequate grandfathering and transition periods, proportionate fees for small and low-volume suppliers, a single transparent testing process and a clear allocation of responsibility between manufacturers and downstream sellers. The gematik criteria and the sickness-fund audit guideline should be notified before adoption if they contain compulsory technical requirements.

EUDI Wallet Interoperability

Section 291(8) provides that the European Digital Identity Wallet will serve as proof of insurance from 1 December 2028. It will serve for authentication in healthcare once the technical conditions are available and no later than 1 December 2030. The same draft provides an EUDI Wallet route for certain identification procedures from 1 January 2027 where the technical conditions exist. The staged

recognition is therefore a deliberate national design rather than a single technical start date. The relevant amendment appears at page 20 of the notified draft.

Article 5f of Regulation (EU) No 910/2014 as amended requires public sector bodies to accept compliant EUDI Wallets where electronic identification and authentication are required for access to their online services. It also requires certain private relying parties that must use strong user authentication, including in health, to accept EUDI Wallets at the user's voluntary request. They must do so no later than 36 months from the date of entry into force of the implementing acts referred to in Articles 5a(23) and 5c(6). The precise application depends on the service, the status of the relying party and the relevant implementing-act trigger. To the extent Article 5f applies, however, a later national date cannot postpone the directly applicable Union obligation.

A cross-border telemedicine provider, mail-order pharmacy or digital health service should not have to maintain a Germany-specific health identity path for years after it must support a Union wallet elsewhere. Parallel identity routes increase integration cost and can make remote use less reliable. The draft should therefore state expressly that the earlier directly applicable Union deadline prevails, bring national readiness dates forward where necessary and prevent additional national certification or in-person requirements for a valid EUDI Wallet transaction.

Effects on the Sectors Represented by bevh

Telemedicine Services

Telemedicine providers depend on discoverability, appointment booking, needs assessment, referrals, authentication and secure follow-on communication. Sections 345a and 360c can make the KBV route the default point of entry, while sections 73(9a), 73(9b) and 370c condition integration on national procedures. A provider established in another Member State may remain legally entitled to offer a service but lose practical access to the insured user journey. Equal access therefore requires more than a formal statement of non-discrimination. It requires published interfaces, equal presentation of qualified services, objective routing criteria, portability of assessment results and an enforceable option, but not an obligation, to connect. Providers must remain free to operate independent booking and care pathways without regulatory or practical disadvantage.

The draft should also ensure that the needs-assessment logic treats telemedicine as an independent and equal care pathway whenever clinically appropriate. The July draft's consultation of health information technology and medical technology associations is welcome, but it does not expressly ensure participation by associations representing providers of digital and telemedicine care services. Those providers should be represented in the section 360b process; consultation alone does not provide an individual market-access right or remedy a governance conflict.

Mail-order Pharmacies

The digital patient journey may extend from appointment booking and telemedicine to electronic prescriptions and the subsequent supply of medicinal products. The design of a publicly mandated digital gateway can therefore also affect downstream access to lawful pharmacy services, including

cross-border distance-selling services. The notified draft contains no express general requirement that an electronic prescription be redeemed in person. Section 339(1b) can support remote access to ePA data by allowing prescription access data to demonstrate the required temporal connection. bevh therefore does not allege a standalone restriction on mail-order pharmacies on that basis. The concern lies in the design and implementation of the connected identity, ePA, prescription and digital access systems.

The final law and its technical specifications should ensure that a secure digital proof of patient presence, identity or insurance does not require physical presentation of a card or an in-person contact. Where the notified digital architecture or its implementing rules provide or control a route to prescription dispensing or pharmacy selection, all eligible pharmacies, including mail-order pharmacies and pharmacies established in another Member State that may lawfully serve the patient, should remain findable and selectable. Any search, default, ranking, routing or integration function within that state-mandated pathway should operate on transparent, objective and non-discriminatory terms and must not privilege a particular pharmacy or distribution channel. Consent and technical confirmation for lawful cross-border prescription redemption should be capable of completion digitally without a media break.

Connected Health Products

Section 374a concerns connected aids and implants reimbursed by statutory health insurance and may affect manufacturers, importers, distributors and online retailers of those products. It does not appear to impose a comparable new requirement on ordinary over-the-counter goods, cosmetics, food supplements or unconnected wellness products. Downstream specifications should neither expand this scope nor transfer manufacturer-level duties to sellers without a clear legal basis.

Requested Action

For the reasons set out above, bevh asks the Commission and the Member States to issue a detailed opinion under Article 6(2) of Directive (EU) 2015/1535 and to request that Germany amend or delimit the notified measure before adoption as follows.

1. Amend or delimit sections 73(9a), 73(9b), 291(8), 345a, 360c, 363e, 370c and 374a so that they do not create disproportionate obstacles for providers and products from other Member States. Essential limits and safeguards should be fixed directly in the statute, and Germany should demonstrate why less restrictive alternatives would not achieve the stated objectives.
2. Replace the prior agreement in section 363e with advance notification as the default. If prior agreement is retained for demonstrably high-risk cases, define an exhaustive scope, objective criteria, a short decision period, deemed agreement, written reasons and independent appeal.
3. Amend the KBV approval and confirmation procedures so that essential criteria are fixed in law, decisions are time-limited and reasoned, equivalent evidence is recognised and independent review is available. Before the agreement under section 370c is concluded, affected platform providers and their representative associations, including those representing providers established in other Member States, should be consulted. Any material requirements that Germany may lawfully apply should govern functionally comparable public and private systems alike.

4. Ensure open, interoperable, technology-neutral and non-exclusive access to the digital care gateway, booking and needs-assessment architecture through published interfaces, equal visibility, transparent and objective routing and an enforceable option, but not an obligation, for qualified private systems to connect. Independent booking and care pathways must remain possible without regulatory or practical disadvantage. Associations representing providers of digital and telemedicine care services should be expressly involved in the section 360b agreement, and the resulting rules should treat telemedicine as an independent and equivalent care pathway wherever clinically appropriate.
5. Implement section 374a without a Germany-specific second product approval. Recognise Union standards, certificates and equivalent tests; provide platform-neutral specifications, proportionate fees and adequate transition rules; and clarify the responsibilities of manufacturers and downstream sellers.
6. Align section 291(8) and all implementing measures with Article 5f of Regulation (EU) No 910/2014 as amended. State expressly that, where applicable, directly applicable Union acceptance duties prevail and that no additional national identity or in-person requirement may defeat a valid EUDI Wallet transaction.
7. Notify the agreements, guidelines, test criteria and technical specifications adopted under the identified provisions before they become binding whenever they constitute technical regulations or rules on information society services within Directive (EU) 2015/1535.
8. Preserve the positive elements of the draft, including open and standardised interfaces, the express commitment to non-discriminatory access, consultation of relevant industry associations and remote-capable proof mechanisms, while converting those principles into enforceable rights and procedures.

bevh remains available to explain the sector-specific effects and to contribute to proportionate technical solutions. The requested amendments would allow Germany to pursue patient safety, security and interoperability without creating avoidable national barriers in the internal market.

Legal Sources

The page references to the German provisions refer to the notified draft dated 9 July 2026. The links below point to the official TRIS and EUR-Lex records.

[1] TRIS notification 2026/0378/DE and notified draft D-2026-0378-DE-01 notified on 13 July 2026

[2] Directive (EU) 2015/1535 OJ L 241 17 September 2015 page 1 especially Articles 1 5 and 6

[3] Treaty on the Functioning of the European Union especially Articles 34 36 49 56 and 168 paragraph 7

[4] Directive 2000/31/EC on electronic commerce OJ L 178 17 July 2000 page 1 especially Articles 3 and 4; Judgment of the Court of Justice of 9 November 2023, Google Ireland and Others, C-376/22, EU:C:2023:835, especially paragraphs 47 to 60; Judgment of the Court of Justice of 30 May 2024, Airbnb Ireland and Amazon Services Europe, Joined Cases C-662/22 and C-667/22, EU:C:2024:432, especially paragraphs 70 to 71 and 85 to 87

[5] Directive 2011/24/EU on patients' rights in cross-border healthcare OJ L 88 4 April 2011 page 45 especially Article 3 point d

[6] Regulation (EU) No 910/2014 as amended by Regulation (EU) 2024/1183 OJ L 2024 1183 30 April 2024 especially Article 5f

[7] Regulation (EU) 2017/745 on medical devices OJ L 117 5 May 2017 page 1 especially Articles 1(15) and 24

[8] Regulation (EU) 2023/2854 on harmonised rules on fair access to and use of data OJ L 2023 2854 22 December 2023 especially Articles 3 to 5 and 44

[9] Regulation (EU) 2025/327 on the European Health Data Space OJ L 2025 327 5 March 2025